ANALYTICAL RESEARCH LABORATORIES

840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

Invoice #80438 (10/2/12)

ARL #: 188140-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injectic
DATE RECEIVED: 09/26/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Four 2 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Fungal	Sterile / Not Sterile	**Not Sterile**	MBI-114	09/26/2012

10/08/12

Amar Arafat - Microbiologist

10/08/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V 5 08/20/2012

ARLOK029703